

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name

Neurovit Forte Tablet

1.2 International Non-Proprietary Name

Vitamin B Complex

1.3 Strength

Each tablet contains:

Thiamine Mononitrate	242.5 mg
Pyridoxine HCl	250.0 mg
Cyanocobalamin	1.0 mg

1.4 Pharmaceutical Dosage Form

Tablet

2. Quality and Quantitative Composition:

Ingredients	mg/ tablet	Function	Reference monograph
Thiamine mononitrate	242.50	Active ingredient	BP
Pyridoxine hydrochloride	250.00	Active ingredient	BP
Cyanocobalamin	1.40*	Active ingredient	BP
<u>Other Ingredients</u>			
Hydroxypropyl methylcellulose E-15	5.00	Binder	USP
Sodium starch glycolate	10.00	Disintegrant	BP
Polyvinylpyrrolidone K25	10.00	Binder	USP
Cornstarch	18.00	Binder	USP
Lactose monohydrate	30.00	Diluent	BP
Colloidal silicon dioxide	2.00	Glidant	USP
Magnesium stearate	5.00	Lubricant	BP
Lactose monohydrate DC	20.00	Diluent	BP
<u>Sub-Coating Solution</u>			
Isopropyl alcohol**	11.88	Solvent	USP
Hydroxypropyl methylcellulose E-5	0.356	Polymer	USP
Kollidon VA-64	1.188	Polymer	USP
<u>Film-Coating Solution</u>			
Propylene glycol	1.80	Plasticizer	BP
Isopropyl alcohol**	5.40	Solvent	USP
Iron oxide yellow	0.06	Colourant	USP
Sunset yellow lake	0.12	Colourant	In-house
Talc	3.24	Glidant	USP

Titanium dioxide	5.22	Colourant	BP
Hydroxypropyl methylcellulose E-5	5.40	Polymer	USP
Hydroxypropyl methylcellulose E-15	5.40	Polymer	USP
<u>Polishing Solution</u>			
Isopropyl alcohol**	0.27	Solvent	USP
Hydroxypropyl methylcellulose E-5	0.18	Polymer	USP
Propylene glycol	0.18	Plasticizer	BP
Hydroxypropyl methylcellulose E-15	0.27	Polymer	USP

3. Pharmaceutical Form

White coloured film-coated oval shaped tablets, shallow convex faces, plain on both side

4. Clinical Particulars

4.1 Therapeutic Indications

For treatment of peripheral neuropathy and neuralgias.

4.2 Contraindications

Not recommended for patients with Leber's disease since optic nerve atrophy may occur.

4.3 Posology and Method of Administration

Adults: Oral, 1 tablet daily, or as directed.

Children: As directed by the physician.

4.4 Special Warning and Precautions for Use

- Caution in patients with history of gout or hepatic disease.
- Do not exceed the recommended dosage during self-medication with Neurovit Forte Tablet; and follow physician's directions if medication is prescribed.

4.5 Drug Interaction

Neurovit Forte Tablet may reduce the effects of levodopa.

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machine

None known

4.8 Undesirable effects

Diarrhoea and itching may occur occasionally.

4.9 Overdose

Neurovit Forte Tablet is usually well tolerated.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Cyanocobalamin acts as a coenzyme for fat an essential for growth, cell replication, haematopoiesis and nucleoprotein and myelin synthesis. Thiamine pyrophosphate and pyridoxal phosphate, the physiologically active forms of thiamine and pyridoxine respectively, act as coenzymes for various metabolic functions affecting protein, carbohydrate and lipid metabolism.

5.2 Pharmacokinetic Properties

The B vitamins are readily absorbed orally except in malabsorption syndromes, metabolised in the liver and excreted via the kidneys.

5.3 Preclinical Safety Data

Not Available

6. Pharmaceutical Particulars

6.1 List of Excipients

Hydroxypropyl methylcellulose E-15
Sodium starch glycolate
Polyvinylpyrrolidone K25
Cornstarch
Lactose monohydrate
Colloidal silicon dioxide
Magnesium stearate
Lactose monohydrate DC
Isopropyl alcohol**
Hydroxypropyl methylcellulose E-5
Kollidon VA-64
Propylene glycol
Isopropyl alcohol**
Iron oxide yellow
Sunset yellow lake
Talc
Titanium dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years from date of manufacture

6.4 Special precautions for storage

Store below 25°C. Protect from light and freezing.

6.5 Nature and Contents of Container

Immediate Container / Packaging

Blister Pack

Type:

Push-through blister pack; the package consists of a transparent thermoformable plastic material and a heat-sealable lacquered backing material.

Material:

Thermoformable plastic material: Polyvinyl Chloride (PVC)

Backing Material: Aluminium Foil

7. Marketing Authorization Holder

Name : Hovid Bhd.

Address : 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30100 Ipoh, Perak, Malaysia.

8. Manufacturer and Manufacturing Site

Name : Hovid Bhd.

Address : Lot 56442, 7½ Miles, Jalan Ipoh/ Chemor,
31200 Ipoh, Perak, Malaysia

9. Date of First Authorization / Renewal of the Authorization

NIL

10. Date of Revision of Text

April 2023